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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/686,835 | 10/16/2003 | George Kukolj | 13/083-2-C1 | 8470 |
| 28513 | 7590 | 12/30/2005 | EXAMINER | |
| MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368 | | | LI, BAO Q | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1648 | | |
| DATE MAILED: 12/30/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/686,835 | KUKOLJ ET AL. | |
| | Examiner | Art Unit | |
| | Bao Qun Li | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09/19 & 10/18/2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,4 and 10-13 is/are rejected.
- 7) Claim(s) 10-13 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

1. This is a response to the amendment filed 09/19 /2005 and 10/18/2005. The specification has been amended and claim 1 has been amended. New claims 10-13 have been added, Claims 1, 3-13 are pending before the examiner. Claims 5-9 were withdrawn from the consideration.
2. Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-4 and 12-13 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, for reasons set forth in the objection to the specification.

5. It appears from reading the specification that for a successful use of the claimed host cell comprising a self-replicating HCV polynucleotide, the host cell line entailed in claims 1, 3-4 is an essential element. The specification does not provide a reproducible method to make the isolated host cell expressing the particular self-replicating HCV polynucleotide or point to any direction to obtain such host cell. Hence, it would require an undue experimentation to enable the invention. Therefore, for claims that need host cell comprising self-replicating HCV replicon or obtaining such self-replicating HCV replicon, deposits of the particular host cell comprising successfully transfected HCV replicon is required.

6. Applicants traverse the rejection and submitted that no deposit is required for the claimed cell because the examiner does not establish a reasonable basis for this enablement rejection.

7. Applicants' argument has been fully considered, however, it is not found persuasive because the specification does not teach that the claimed HCV encoded by the particular

Art Unit: 1648

polynucleotide can be successfully expressed as a infectious HCV and replicated well in any or all kind of cell lines, and the state of art does not teach that HCV replicon can be successfully replicate well in any or all kind of cell origins. The particular cell line that can support the HCV replicon to replicate known in the art is hepatoma Huh-7 as evidenced by Lohman et al. (Science 1999, Vol. 285, No. 110-1130) and Blight et al. (Science 2000, Vol. 290, pp. 1972-1974). The specification teaches that only one of the Hut 7 cell line clone S22.3 is able to support the claimed HCV replicon to replicate and express without killing the host cell (page 19).

8. For the reasons discussed above, it is apparent that the host cell line S22.3 are required to practice the claimed invention. As a required element they must be known and readily available to the public or obtainable by repeatable method set forth in the specification, or otherwise readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposits of the particular HCV replicon transfected host cell line and/or deposits of the recited HCV self-replicon constructs See 37 CFR 1.802.

New matter

9. The amendment filed on 09/19/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (1). Claims 10-13 that are directed the HCV polynucleotide is SEQ ID NO: 24 or SEQ ID NO: 25. However, the polynucleotide of SEQ ID NO: 24 and SEQ ID NO: 25 do not contain the mutation at the position 2042 from G to C or from G to R as the specification originally filed (1233 from the coding sequence as applicants suggested). Applicant is required to cancel the new matter in the reply to this Office Action.

New matter Rejection

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

Art Unit: 1648

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the new claims 10-13 contain new matter because they are directed to the cited HCV polynucleotide as SEQ ID NO: 24 or SEQ ID NO: 25, after the specification has been carefully reviewed, it is found that the polynucleotide of SEQ ID NO: 24 or SEQ ID NO: 25 does not contain the mutation from G to C or from G to R at the position 2042 as the specification originally filed (1233 from the coding sequence as applicants suggested). Therefore, this is new matter, and applicants do not have possession for having these claimed host cell line comprising said mutated HCV polynucleotide.

12. Applicants are suggested to cancel the new matter in the claims in order to overcome the rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

12/23/2005



JEFFREY STUCKER
PRIMARY EXAMINER